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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30-day notice]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer, faxed to OMB at 202-395-5806.

Proposed Project: Protection of Human Subjects: Assurance Identification/IRB

Certification/Declaration of Exemption Form Extension – OMB No. 0990-0263 - Office for Human Research Protections

Abstract: The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)]. The Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. Respondents are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule). There are an estimated total of 25,000 human research studies supported each year, an average of 2 certifications per institutions and an estimated one-half hour per certification, for a total burden of 12,000 hours. Data is collected as needed.

Estimated Annualized Burden in Hours for IRB Certification Burden

Form name	Number of Respondents	Number of Responses per Respondent	Hours per Response	Response Burden Hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	12,000	2	30/60	12,000

Keith A. Tucker

Office of the Secretary

Paperwork Reduction Act Clearance Officer

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